

body region, which, for the purpose of illustration, can be the lower esophageal sphincter, or cardia, or both. The applied energy creates one or more lesions, or a prescribed pattern of lesions, below 5 the mucosal surface of the esophagus or cardia. The subsurface lesions are formed in a manner that preserves and protects the mucosal surface against thermal damage.

It has been discovered that natural healing 10 of the subsurface lesions leads to a physical tightening of the sphincter and/or adjoining cardia. The subsurface lesions can also result in the interruption of aberrant electrical pathways that may cause spontaneous sphincter relaxation. In any 15 event, the treatment can restore normal closure function to the sphincter.

The structure of the operative element 12 to achieve this result can vary. A representative embodiment is shown in Figs. 2 to 4, in which the 20 operative element 12 comprises a three-dimensional basket 56. The basket 56 includes one or more spines 58, and typically includes from four to eight spines 58, which are assembled together by a distal hub 60 and a proximal base 62.

In the illustrated embodiment, an 25 expandable structure 72 comprising a balloon is located within the basket 56. The balloon structure 72 can be made, e.g., from a Polyethylene Terephthalate (PET) material, or a polyamide (non-compliant) material, or a radiation cross-linked polyethylene (semi-compliant) material, or a latex material, or a silicone material, or a C-Flex

(highly compliant) material.

The balloon structure 72 presents a normally, generally collapsed condition, as Fig. 2 shows. In this condition, the basket 56 is also 5 normally collapsed about the balloon structure 72, presenting a low profile for deployment into the esophagus 10.

The catheter tube 30 includes an interior lumen, which communicates with the interior of the balloon structure 72. A fitting 76 (e.g., a syringe-activated check valve) is carried by the handle 28. The fitting 76 communicates with the lumen. The fitting 76 couples the lumen to a syringe 78 (see 10 Fig. 3). The syringe 78 injects fluid under pressure through the lumen into the balloon 15 structure 72, causing its expansion.

Expansion of the balloon structure 72 urges the basket 56 to open and expand (see Fig. 3). The force exerted by the balloon structure 72, when expanded, is sufficient to exert an opening force 20 upon the tissue surrounding the basket 56.

Each spine 58 carries an electrode 66 (see Fig. 4). In the illustrated embodiment, each electrode 66 is carried within the tubular spine 58 25 for sliding movement. Each electrode 66 slides from a retracted position, withdrawn in the spine 58 (shown in Fig. 3) and an extended position, extending outward from the spine 58 (see Fig. 4) through a hole in the spine 58. A push-pull lever 68 on the handle 28 is coupled by one or more interior wires 30 to the sliding electrodes 66. The lever 68 controls movement electrodes between the retracted position

(by pulling rearward on the lever 68) and the extended position (by pushing forward on the lever 68). The electrodes 66 have sufficient distal sharpness and strength, when extended, to penetrate 5 a desired depth into tissue the smooth muscle of the esophageal or cardia 20 wall. The desired depth can range from about 4 mm to about 5 mm.

In this arrangement (see Fig. 1), the system 10 includes a generator 38 to supply the treatment energy to the electrodes 66. In the illustrated embodiment, the generator 38 supplies 10 radio frequency energy, e.g., having a frequency in the range of about 400 kHz to about 10 mHz. Of course, other forms of energy can be applied, e.g., coherent or incoherent light; heated or cooled 15 fluid; resistive heating; microwave; ultrasound; a tissue ablation fluid; or cryogenic fluid.

A cable 40 extending from the proximal end 20 of the handle 28 terminates with an electrical connector 42. The cable 40 is electrically coupled to the operative element 12, e.g., by wires that extend through the interior of the handle 28 and catheter tube 30. The connector 42 plugs into the generator 38, to convey the generated energy to the 25 operative element 12.

The electrodes 66 are formed of material 30 that conducts radio frequency energy, e.g., nickel titanium, stainless steel, e.g., 304 stainless steel, or a combination of nickel titanium and stainless steel.

In the illustrated embodiment (see Fig. 5), an electrical insulating material 70 is coated about